BEN NIGHTHORSE CAMPBELL
COLORADO

United States Senate

WASHINGTON, DC 20510-0605

September 9, 1998

Michael A. Friedman, MD
Acting Commissioner
Food and Drug Administration
The Parklawn Building, Room 14-71
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Friedman:

I am writing in reference to the upcoming implementation of the Food and Drug Administration (FDA) Modernization Act (P.L. 105-115) which was passed last year, specifically as it addressed pharmacy compounding.

In the past few months, many Coloradans have expressed to me their concerns regarding compounding, the process by which a pharmacist combines, mixes or alters ingredients to create a medication for a patient, at the direction of a physician. The FDA Modernization Act recognized compounding as an element of the practice of pharmacy that was to be regulated by the states, but distinguished it from "manufacturing" which falls within the jurisdiction of the federal Food and Drug Administration.

As the FDA will now issue implementing regulations, I would like to underscore what I believe is the intent of Congress:

- The practice of compounding, to the extent it has been addressed federally, falls within the province of state regulatory authorities. Collaboration between the FDA and state regulatory authorities in developing the regulations required by the new statute will support those state authorities in their oversight of compounding activity.

- In order for compounding to meet the needs of physicians and patients, the FDA should ensure that the full spectrum of bulk substances is available when the provision becomes effective in November. It is important that the review and listing of bulk drug substances be expeditious, and include collaboration with both the United States Pharmacopeia and the FDA Compounding Advisory Panel.

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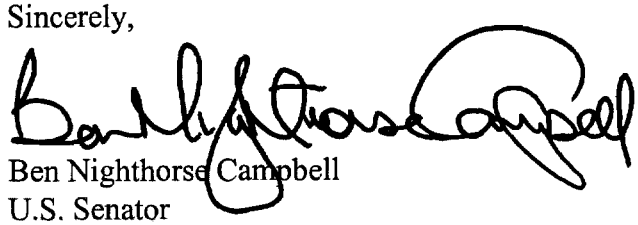
- It is important that the Compounding Advisory Panel include representatives from the professional and private sectors to best assist the FDA in understanding the practice of compounding and how it is distinguished from manufacturing.

I would like to commend the FDA for it's prompt action in establishing the Compounding Advisory Panel. Thank you for your attention to these important issues and for keeping me apprised of further developments in the implementation process.

Sincerely,



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